

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-310

Pioneer Product: 113-645
Trade Name: estroPLAN™ Injection
Ingredients: Cloprostenol sodium
Sponsor: Parnell Laboratories (Aust) Pty. Ltd.
Approval Date: May 13, 2004
Status: Prescription only
Route: Intramuscular
Species: Cattle, beef and dairy
Drug Form: Liquid (solution)
Concentration: 250 micrograms per milliliter.
Indications: To induce luteolysis in beef and dairy cattle, terminate pregnancies from mismatings, and to treat certain conditions associated with prolonged luteal function.
Tolerance: Not required.
Withdrawal: None

21CFR 522.460 & 510.600

ANADA Number: 200-372

Pioneer Product: 055-060
Trade Name: Han-Pen™
Ingredients: Penicillin G Potassium
Sponsor: G.C. Hanford Manufacturing Co.
Approval Date: May 21, 2004
Status: Over-the-counter
Route: Oral
Species: Turkeys
Drug Form: Powder (soluble)
Concentration: 0.5 billion units penicillin G potassium per foil bag (313 grams).
Indications: For the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.
Tolerance: 21CFR 556.510 Penicillin: A tolerance of 0.01 part per million is established for penicillin and the salts of penicillin residues in the uncooked edible tissues of turkeys.
Withdrawal: One day

21CFR 520.1696b

ANADA Number: 200-328

Pioneer Product: 124-241
Trade Name: Oxytocin Injection
Ingredients: Oxytocin
Sponsor: Cross Vetpharm Group Ltd.
Approval Date: May 21, 2004
Status: Prescription only
Route: Intravenous, intramuscular, or subcutaneous
Species: Horses, mares; cattle, cows; sheep, ewes; swine, sows
Drug Form: Liquid (solution)
Concentration: 20 U.S.P. units per milliliter
Indications: As an aid in the management of parturition in the following ways: precipitate labor; accelerate normal parturition; facilitate postpartum evacuation of uterine debris; facilitate postoperative contraction of the uterus following a cesarean section, and control of uterine hemorrhage. Also serves to contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.
Tolerance: Not required.
Withdrawal: None

21CFR 522.1680

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Change of Sponsor

NADA Numbers: 007-076, 008-244, 043-215, & 092-150

From: PM Resources, Inc.
To: Virbac AH, Inc.
3200 Meacham Blvd.
Ft. Worth, TX 76137
Drug labeler code: 051311

Addition of Sponsor

Parnell Laboratories (Aust) Pty. LTD.
Century Estate, Unit 6
476 Gardeners Rd.
Alexandria, New South Wales 2015, Australia

Drug Labeler Code: 068504

Correction of Patent Information

NADA Number: 141-035
Patent Numbers: 4,798,837
5,416,102
Expiration Dates: May 16, 2012
January 17, 2006

NADA Number: 141-084
Patent Number: 5,994,395
Expiration Date: February 15, 2016

NADA Number: 141-105
Patent Numbers: 4,798,837
5,416,102
Expiration Dates: January 17, 2006
May 16, 2012

NADA Number: 141-175
Patent Number: 5,750,548
Expiration Date: May 23, 2012

NADA Number: 141-204
Patent Numbers: 5,750,548
5,994,395
Expiration Dates: May 23, 2012
February 15, 2016

NADA Number: 141-205
Patent Numbers: 5,750,548
4,798,837
Expiration Dates: May 23, 2012
January 17, 2006

Actions Taken by FDA Center for Veterinary Medicine

Suitability Petition Action

Number: 04P-0175/CP1
Sponsor: Intervet, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristic(s): The generic product will have a change in strength (concentration) from the pioneer.
Action: Approved on April 28, 2004.